

Remarks

Claims 12-35 are pending.

Rejection under 37 CFR § 112, First Paragraph

Claims 11-35 are rejected under 35 USC § 112, first paragraph, as lacking enablement.

The Examiner refers to Taira, *No To Shinkei*, 44(1):61-63 (1992) to reject the claims as lacking enablement, absent evidence to the contrary.

Taira, *No To Shinkei*, 44(1):61-63 (1992) reports that two patients who were receiving zonisamide for the treatment of epilepsy experienced side effects of tremors.

The Examiner asserts that the rejection will be maintained “absent evidence to the contrary.” Applicant respectfully directs the Examiner’s attention to the application which provides evidence to the contrary, i.e., that zonisamide is useful in the claimed methods. Example 5 from the specification at page 16, lines 5-18, shows that zonisamide is useful in human patients for the claimed methods:

Zonisamide was used in treatment of patients at an outpatient neurology clinic, which provided the following results. Adverse reactions experienced in treatment were GI upset, somnolence and skin rash. Kidney stones and anhydrosis (lack of sweating) were not encountered in the patients treated. For intractable essential tremor, 10 patients (age range: 46 to 82) were identified who were either intolerant to, or failed on, primidone or propranolol therapy. The dosage of zonisamide to these patients was 100 mg to a maximum of 200 mg once daily. The study dose was continued for at least 12 weeks unless discontinued earlier due to side effects. Of the ten patients, who did not respond to other treatment, four patients responded by reduction in tremor of greater than 50% and reported a better quality of life. Amongst other categories: mixed tremor (non-essential, secondary to trauma or multiple sclerosis), two out of two patients responded; multi-infarct-related (2 or more minor strokes) tremor, one out of two patients responded; and in Parkinsonian tremor, two out of four responded.

Applicant respectfully submits that the data in the specification provides the necessary evidence to successfully rebut the § 112 rejection. In view thereof, Applicant respectfully requests that the rejection under 35 USC § 112, first paragraph, be withdrawn.

Response and Amendment under 37 CFR § 1.116

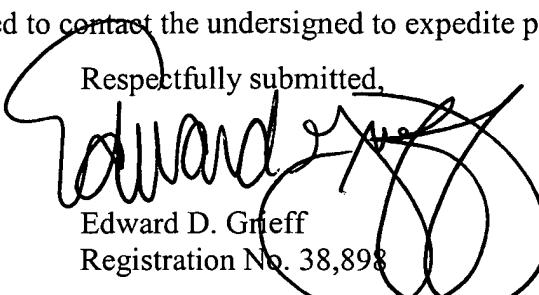
US Application No. 10/663,187

Page 3 of 3

Conclusion

An early and favorable consideration and allowance of claims 12-35 is respectfully requested. The Examiner is encouraged to contact the undersigned to expedite prosecution.

Respectfully submitted,


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